

GENERAL INFORMATION

Chemical Composition

All the ingredients used in capsule manufacture comply with applicable regulatory requirements.

Gelatin

Pharmaceutical grade gelatin complies with IP. Gelatin is extracted from collagen, the major structural protein in connective tissue and bone. Gelatin is classified as a protein food being composed of eighteen amino acids, but when viewed as a single protein source, gelatin is not a “Complete protein” because it has a low proportion of certain amino acids. Gelatin is a good source of the essential amino acid lysine. Gelatin is made up of amino acids joined together by peptide linkages.

- Ø Chemical Properties
- Ø Physical Properties
- Ø General Properties

Free Of Microbial Contamination

Water

Water complies with IP & In-house Specification. We are using R.O. Water for our entire process.

Colorants

Colours used comply with BIS or Code of Federal Regulations (CFR).

Size & Type

SHL capsules are presently available in seven size ranging from 00 to 4. The capsules have positive mechanical lock due to the indentations in cap & body.

Printing

A variety of types of print styles are offered by SHL for product identification and/or dosage information. Straight or circular, single or two colour printing in oriented or Non-oriented form is available.

Printing Ink

All ingredients used in printing ink comply with relevant regulatory requirements.

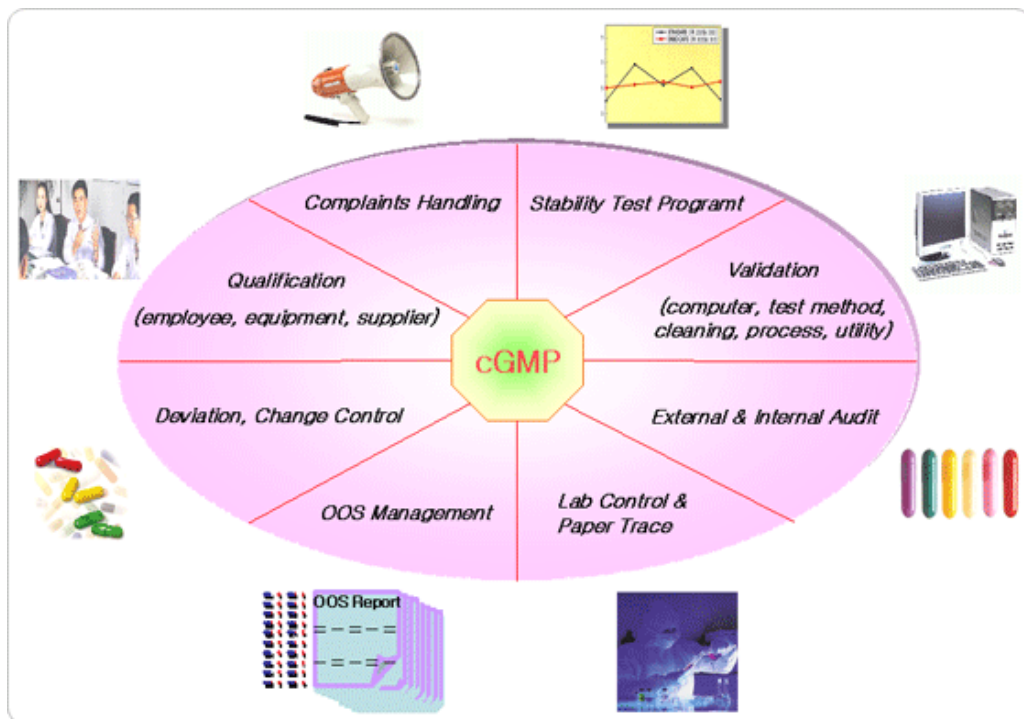
Permitted Colours : Permitted azo dyes comply with the

requirements of BIS and CFR specifications for food Colours

COLOUR	NAME OF COLOUR	C.I. REF.CODE	COLOUR INDEX No.	EEC No.	CFR FD & C No.
Red	Erythrosine	Red 14	45430	127	Red 3
	Carmoisine	Red 3	14720	122	-
	Ponceau 4R	Red 7	16255	124	-
Blue	Iron Oxide	NA	77491	172	NA
		Blue 2	42090	133	Blue 1
	Brilliant Blue	Blue 1	73015	132	Blue 2
Yellow	Tartrazine	Yellow 4	19140	102	Yellow 5
		Yellow 3	15985	110	Yellow 6
	Sun Set Yellow	Yellow 13	47005	104	
Opacifier	Quinoline Yellow	NA	77492	172	D & C Yellow 10
	Iron Oxide	NA	77891	171	NA
Black	Titanium Oxide				NA
		Iron Oxide	NA	77499	172
					NA

Color Sample	Color Name	Dyes	Remarks
	White op.	Titanium Dioxide	Mineral Dyes
	Reddish Brown op.	Iron Oxide Red Caramel	Mineral Dyes Natural Dyes
	Pink op.	Carmine	Natural Dyes
	Yellow op.	Iron Oxide Yellow	Mineral Dyes
	Yellow op.	Riboflavin	Natural Dyes
	Green op.	Copper Chlorophyllin	Natural Dyes
	Amethyst op.	Erythrosine / Tartrazine / Brilliant Blue FCF	FD&C Dyes

SHL Capsule strictly adheres to the quality assurance procedures mandated by cGMP.



CAPSULE FILLING M/C & CONDITIONS



SHL is committed to providing full manufacturing support for our capsule products. Throughout the world, our staff includes Technical Service Engineers who provide direct, “hands on” support to our customers. Trained and experienced with all major types of capsule filling machines, these engineers work with shop floor operators and managers to not only resolve problems, but also to increase machine productivity by preventing issues from occurring in the first place.

If a filling problem arises, our Technical Service Engineers are available to provide assistance in assessing the issue, and assuring prompt resolution.

In all area of encapsulation, the importance of operating in GMP environment is growing. Our engineers can also assess compliance issues at your facility and provide GMP training for shop floor colleagues.

Area Conditions: The Moisture content of capsules is directly related to relative humidity of air to which they are exposed. Capsules are removed from their packaging and exposed during the filling process. Particular care needs to be taken to ensure their optimum performance with specific reference to high speed filling machines. The ideal conditions for a filling area are temperatures between 20 D.C to 25 D.C and relative humidity 45% to 65%, which will remain the moisture content of the capsules within the desired range of 14.50% to 15.25% w/w.

It is difficult to maintain the above conditions, then expose only the bare minimum quantity of capsules from the box required for immediate filling.

The capsules filling machine may be sited in a controlled area, but the air conditioning system may be operated only during the working day. The empty capsules should preferably be removed from the hopper on the machine, if climatic conditions vary from the ideal in idle hours.

For capsules handling it is best to avoid plastic utensil, because this could result in a static electrical charge, which could cause feeding problems on the filling machine. It is recommended to use metal scoops or containers.

CUSTOMER TECHNICAL SERVICES :



Apart from providing customers with information on quality, SHL capsules also provides technical support in many areas including :

- Ø Colour matching and development of new shades
- Ø Information on dye acceptability
 - Ø Logo design for the printing of capsules
- Ø Assistance on filling machine operations
- Ø Advice on handling and storage of capsules

Note: The information contained herein, to the best of our knowledge, is true and accurate. Recommendations or suggestions are made without warranty or guarantee, since the conditions of storage and use are beyond our control. Any information contained herein is intended as a recommendation for use of our products.

CLEANING

CLEANING STANDARDS

SHL has adopted a policy of utilizing GMP endorsed clothes. Under our cleanliness policy, working clothes are collected, classified & cleaned in the cleaning room more twice a week. Workers are required to wash their hands prior to entering the working place. Workers must also have their hands & feet disinfected & their bodies air- showered prior to entering their work area. In addition SHL makes alcohol impregnated cotton pads available in the work place for workers to use during their operations.

As n added precaution, monthly microorganism test are carried out on working clothes workers hand and gloves.

CLEANING VALIDATION

To prevent the gelatin solution from being contaminated at an early stage, SHL performs the validation test at the melting tank, service tank, dipping pan & other key areas. This procedure helps the company to establish optimum disinfection standards. At the same time SHL performs tests on all tools & vessels, which directly come into contact with capsules to determine the optimum disinfecting and changing frequencies.

SPECIAL FEATURES

SELECTION OF GELATIN

Unless Gelatin that offers high bloom & viscosity is used in the manufacturing process, uniformity problems in capsules film thickness and weight distribution can arises, leading to slower disintegration, in addition , inferior gelatin can cause capsules to break or be deformed during the filling operation, contain bacteria or impurities or process an unpleasant odor. To supply our world-wide customer base with only the finest quality capsules obtainable, SHL uses only gelatin which posses bloom of more than 250.

COLOURS

SHL has many experts with plenty of expertises on colouring. Following table gives the list of Banned Colours in various Countries :

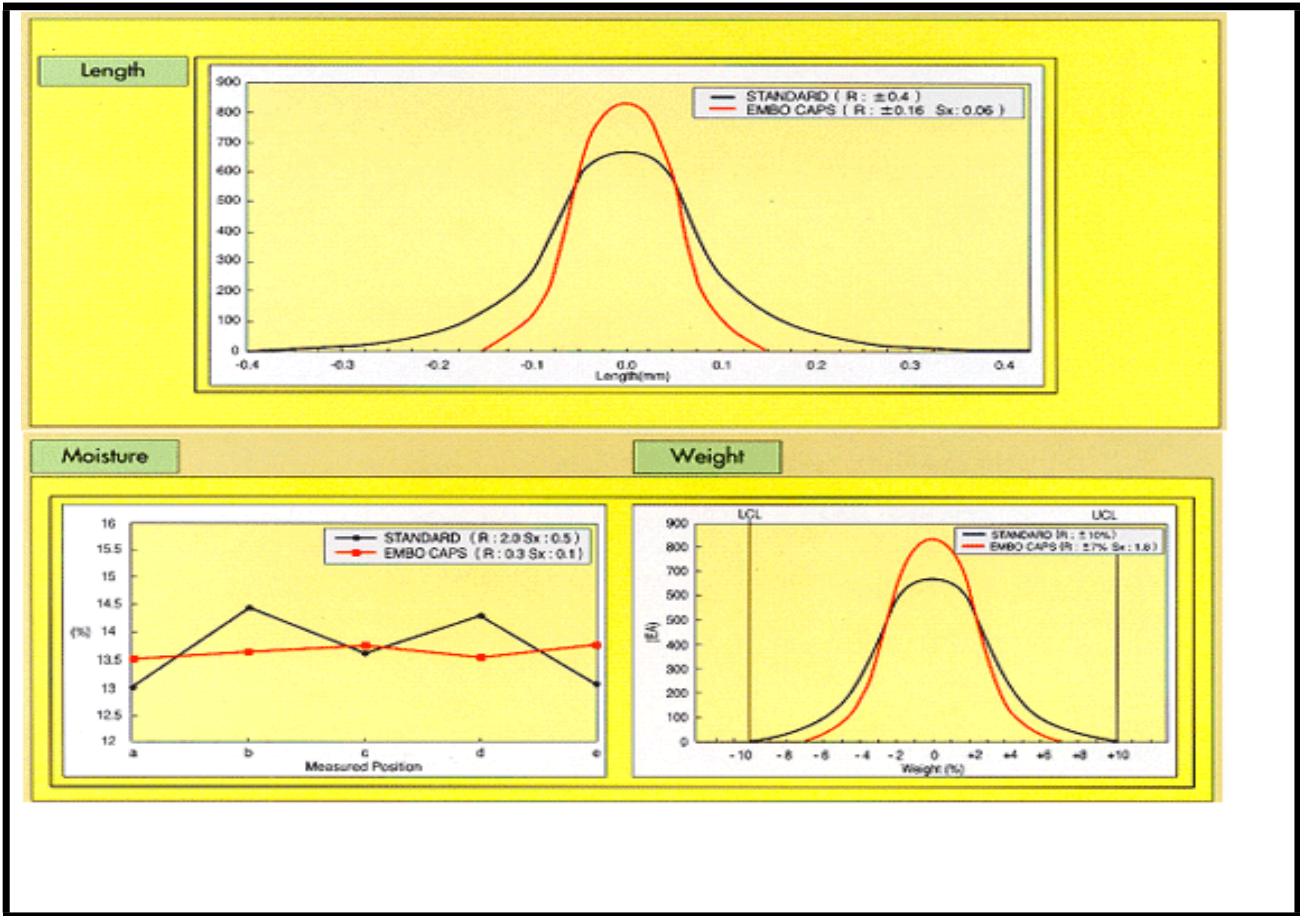
FEATURES OF SHL CAPSULES QUALITY

Gelatin solution viscosity is a key to the strength, weight & plasticity of the capsules film. As one of the SHL manufacturing process the automated viscosity control system greatly serve to maintain the consistency of the weight & film of our capsules. SHL's expertise has led to minimized deviations in capsules length, moisture content & weight. The capsules consistency resulted in bringing more stability and runability to our worldwide valued customers.

Automatic Viscosity Control System : With SHL automatic viscosity control system, deviation in the weight of capsules are effectively controlled because the viscosity of the gelatin can be easily adjusted by adding water to the gelatin solution at different process stages.

Film Distribution : Capsules film should be uniformly distributed several factor affect the film distribution including : Temperature of the mold pin and of the gelatin solution, air temperature and humidity, duration of dipping, machine speed, gelatin properties, viscosity control system & drying method.

The Length, Weight and Moisture content of SHL capsules : SHL is committed to research & development to continually improve the quality of their capsules. They greatly reduced the deviation in the length, weight and moisture content of their capsule.

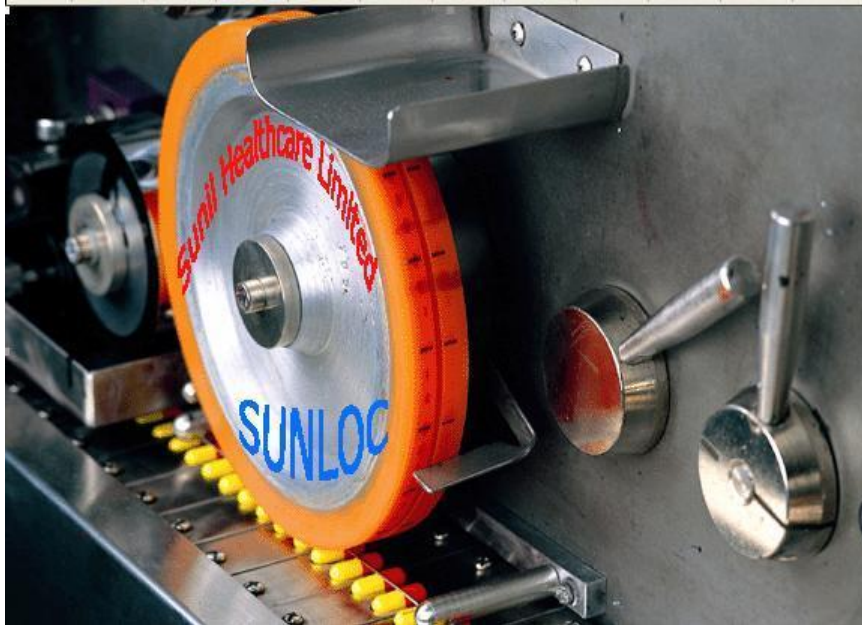


SHL's gelatin capsules have the least deviations in length, moisture content, and weight for superior machinability and stability.

Clear & Precise Printing

SHL capsules are clearly and precisely printed according to customer's specifications. There are two types of printing styles. The most common is axial printing, which printed along the long axis of both the cap and body of the capsules.

The other is radial or spin printing, of which printing is made on the circumference of the capsules. 2 colour printing & rectified printing are other options available to SHL capsule customers. SHL has many sophisticated printing machine.



Ø Printing Range :

SHL has different printing range depends on the capsules size. (00, 0EL, 0,1,2,3,4.).

Ø Kinds of Printing : Axial printing, Rectified Axial printing, Spin Printing & Two colour spin Printing.

Ø A Variety of printing Colours: A Variety of printing colour commonly available include the following eight colour :
White, Red, Blue, Green, Brown, Black, Yellow & Grey. Only Printing inks approved for Pharmaceutical use may be used

IMPLEMENTATION OF SIX-SIGMA

Six-Sigma is a practice to achieving High quality level by on line random sampling procedure with the help of Six-sigma persons. Mainly Six Sigma concern with immediate identification of defects & immediate its rectification. There are two major streps in Six-Sigma.

- **Statical Quality Control: Immediate identification of defects by random sampling**
- **Process Quality Control: Immediate rectification of Defects.**
Purpose of Six Sigma to increase the quality of product for giving diligent to our customer.

Now SHL has implemented the Six - Sigma concept in our plant in which all the Six-sigma persons randomly check all M/C for improving quality of product.